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**(56) Documents Cited**

**GB 2161709 A**

EP 0231634 A2

**WO 95/20419 A1**

WO 95/16485 A1

US 5222487 A

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(58) **Field of Search**

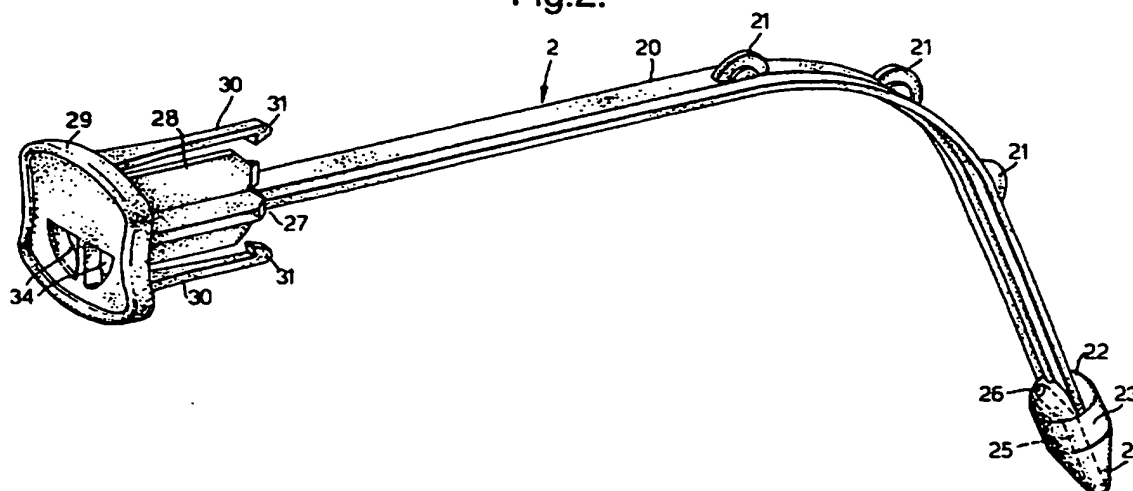
UK CL (Edition 0) A5R RGBB RGEX

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**(54) Tracheostomy Assembly Including Obturator with Connecting Means.**

(57) There is disclosed a medical tube or tracheostomy assembly wherein a one-piece, flexible, plastic obturator 2 is provided with resilient catches 31 at its machine end that engage with lips 14 on the machine end of a tracheostomy tube 1 such that the obturator cannot be rearwardly displaced. The obturator which extends through and beyond the patient end of the tube is of strap-like, rectangular section and provided with a bullet head nose 23 at its patient end. An air passage allowing the patient to breath through the assembly is defined by a bore 25 between the nose tip and its rear, the gap between the rectangular strap 20 and the provision of holes 34 in the flange 29 provided at the machine end of the obturator. The obturator is disengaged by twisting the flange so that the catches come out of alignment with the lips and pulling back.

**Fig.2.**



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Fig.1.

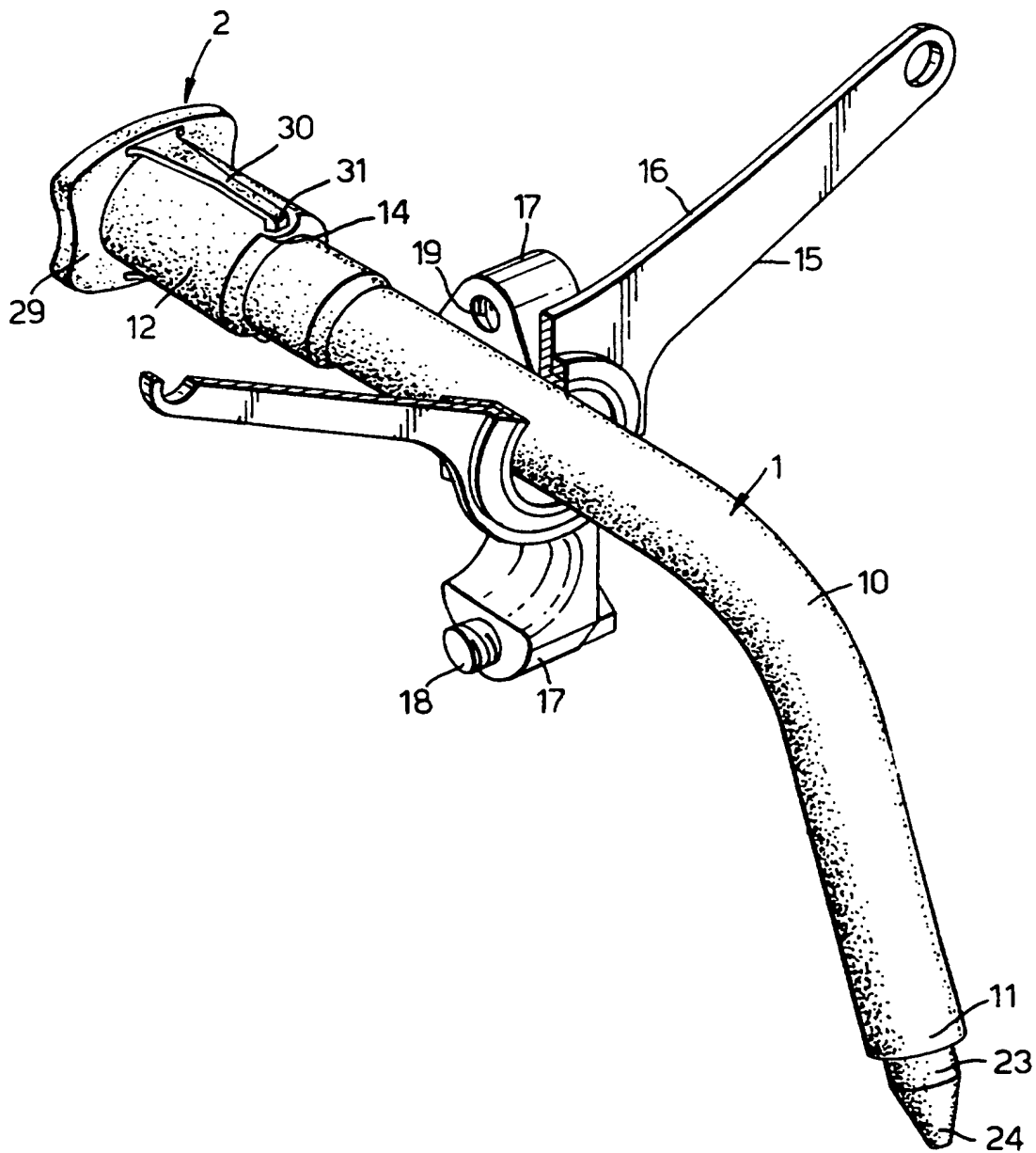


Fig.2.

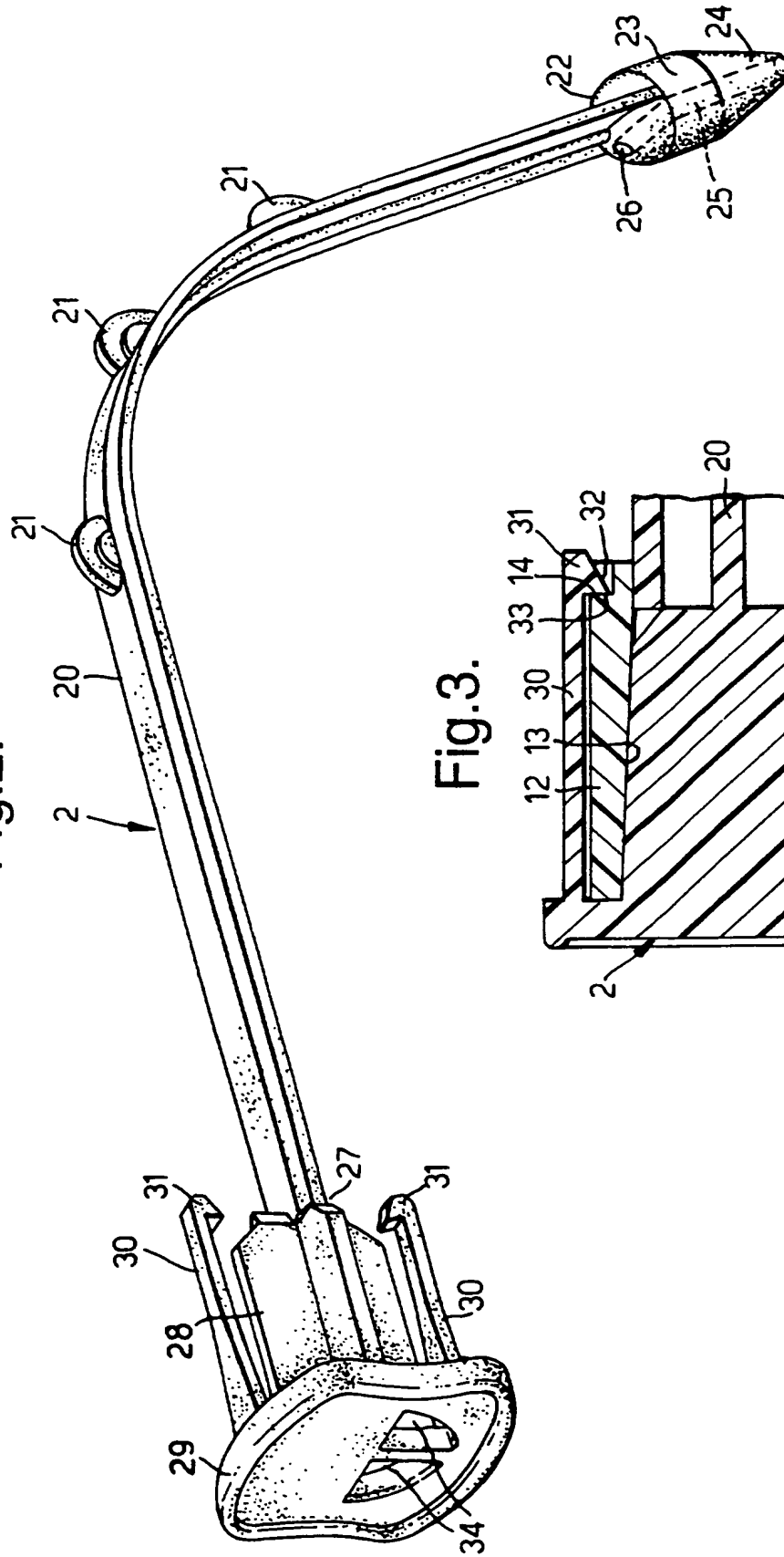
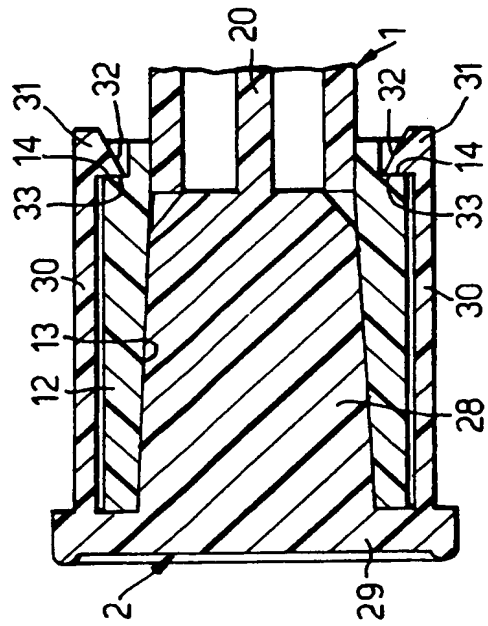


Fig.3.



**MEDICAL TUBE ASSEMBLIES**

This invention relates to medical tube assemblies.

The invention is more particularly concerned with medical tube assemblies of the kind including an outer tube and an obturator inserted within the tube.

Tracheostomy tubes are often inserted with the aid of an obturator having a pointed end projecting from the patient end of the tracheostomy tube. The tip of the obturator helps separate tissue, enabling smooth entry of the tube. The obturator also helps stiffen the tube and prevents ingress of tissue into the tube, which could cause blockage. Examples of tracheostomy obturators are described in US4246897, US5222487 and GB2224213. The obturator is pushed into the tracheal tube to its full extent, as limited by a flange abutting the patient end connector on the tracheal tube. The surgeon has to grip the machine end of the obturator and the tube in order to hold the obturator in place and prevent it being pushed rearwardly out of the tube during insertion. Any displacement of the obturator from its correct position may make insertion of the tube more difficult and, by reducing the smoothness of the patient end of the assembly, may cause trauma to tissue around the stoma. After insertion, the obturator is pulled out of the machine end of the tube. Obturators are also used to help insertion of other medical tubes.

It is an object of the present invention to provide an improved medical tube assembly.

According to one aspect of the present invention there is provided a medical tube assembly comprising a medical tube and an obturator inserted within the tube, the obturator having a patient end projecting from the patient end of the tube to aid insertion of the assembly, the obturator and tube being provided at their machine ends with cooperating surface formations arranged, when engaged, to prevent rearward displacement of the obturator relative to the tube.

The cooperating surface formations are preferably arranged such that they can be disengaged by twisting the obturator through a small angle relative to the tube. The cooperating surface formations may be provided by a resilient catch and a lip. The obturator preferably has two resilient catches extending along opposite sides of the tube and engaging respective lips on the tube. The tube may have a coupling at its patient end, the surface formation on the obturator being provided by at least one resilient catch that extends along the outside of the connector and engages on a surface formation on the connector. The obturator may have a strap of rectangular section extending between its machine end and its patient end. The patient and machine ends of the obturator both preferably have an air passage therethrough. The obturator may be moulded from a plastics material.

According to another aspect of the present invention there is provided a tracheostomy tube assembly comprising a tracheostomy tube and an obturator inserted within the tube, the obturator having a pointed patient end projecting from the patient end of the tube to aid insertion of the assembly, the obturator and tube being provided at their machine ends with cooperating surface formations arranged, when engaged, to prevent rearward displacement of

the obturator relative to the tube, and said tube and obturator together providing an air passage extending along the assembly to enable the patient to breath while the assembly is being inserted.

A tracheostomy tube assembly according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a partly cut-away perspective view of the assembly;

Figure 2 is a perspective view of the obturator of the assembly; and

Figure 3 is a cross sectional side elevation of the machine end of the assembly.

The assembly comprises a tracheostomy tube 1 and an obturator 2.

The tube 1 has a conventional shaft 10 of circular section, which is curved or bent to suit the anatomical requirements of the patient. The patient end 11 of the shaft 10 is cut square and rounded to be atraumatic. At its machine end, the shaft 10 is bonded to a coupling 12 having a female tapered bore 13 shaped to receive a male tapered coupling (not shown) connected to a patient ventilation or anaesthetic circuit. Alternatively, where the patient is breathing spontaneously, the coupling 12 is left open. Externally, the coupling 12 is of cylindrical shape apart from surface formations provided by two, short undercut lips 14 located diametrically opposite one another at the patient end of the coupling. The tube 1 also

includes a conventional, adjustable flange 15 of the kind described in GB2227941. The flange 15 has a flexible plate 16 to which two semi-circular arms 17 are attached and hinged with one another. The arms 17 can be clamped together, to lock the flange 15 at any location along the shaft 10, by means of a bolt 18 on one arm that engages a threaded aperture 19 on the other arm. The shaft 10 has an inflatable cuff (not shown) towards its patient end, for sealing with the inside of the trachea; alternative tubes need not include such a cuff.

The obturator 2 is moulded from a stiff but bendable, resilient plastics material and has a strap 20 of generally rectangular shape extending along the major part of its length, the width of the strap being slightly less than the internal diameter of the shaft 10 of the tube 1. The strap 20 is bent at right angles, to the same shape as that of the shaft 10, and has three semicircular projections 21 on its convex side, in the region of the bend, so that the strap is held substantially centrally within the tube 1 in the region of the bend. At its patient end 22, the obturator is provided with a bullet shape nose 23, which is a close fit within the patient end 11 of the tube 1. The nose 23 has a pointed tip 24, which, in use, projects from the tube 1 so as to form a pointed continuation of the patient end of the shaft 10. A bore 25 extends along the nose 23 from its tip 24 to an opening 26 at its rear end.

At its machine end 27, the obturator 2 has an enlarged, cruciform section 28 with a tapered exterior, which is a close friction fit within the coupling 12 of the tube 1. A flange 29 extends radially at the machine end of the cruciform section 28 and provides a grip by which the obturator 2 can be inserted and removed from the tube 1. Two resilient arms 30 extend forwardly from the flange 29 on opposite sides of the obturator 2. The arms 30 are terminated

at their patient end by surface formations in the form of inwardly-directed catches 31 formed by an inclined ramp 32 and a ledge 33. The dimensions of the arms 30 are such that, when the flange 29 abuts the machine end of the coupling 12, the arms extend along opposite sides of the coupling 12 with the catches 31 engaging under the lips 14, thereby preventing the obturator 2 being removed from the tube. Two vent holes 34 are formed through the flange 29 in alignment with the corners between the cruciform section 28.

In use, the obturator 2 is pushed fully into the tube 1 so that the nose 23 projects from the patient end 11 of the tube and so that the catches 31 engage the lips 14 on the coupling 12. The flexible nature of the strap 20 enables it to be bent during insertion and removal to conform to the shape of the tube 1, without deforming the tube itself. The assembly is inserted in the usual way, the obturator 2 providing a tapered lead into the tracheostomy for the tube 1. Rearward movement of the obturator 2 relative to the tube 1 is prevented by engagement of the catches 31 with the lips 14. The patient can breath through the assembly during insertion because of the bore 25 through the nose, the passage between the strap 20 of the obturator 2 and the inside of the tube, and the holes 34 in the flange 29. When the assembly has been inserted to the correct location, the obturator 2 is removed by gripping the flange 29 and twisting it through about 20° so that the catches 31 come out of alignment with the lips 14 and can be pulled rearwardly along the outside of the coupling 12. After removal of the obturator 2, the coupling 12 can be connected to a ventilation circuit or left open, in the usual way.



The present invention makes insertion of the assembly easier because there is no need to hold the machine end of the obturator. Also, there is no risk of the obturator being displaced rearwardly during insertion, thereby ensuring that damage to the tissue around the stoma is minimized. The provision of the lips on the coupling, at the machine end of the tube do not prevent the tube being connected to conventional couplings. It will be appreciated that the obturator could be locked with the tube against rearward displacement by alternative surface formations on the machine end of the obturator and tube. The invention could be used with tubes, other than tracheal tubes, where it is necessary to prevent displacement of an obturator relative to a tube.

**CLAIMS**

1. A medical tube assembly comprising a medical tube and an obturator inserted within the tube, the obturator having a patient end projecting from the patient end of the tube to aid insertion of the assembly, wherein the obturator and tube are provided at their machine ends with cooperating surface formations arranged, when engaged, to prevent rearward displacement of the obturator relative to the tube.
2. A medical tube assembly according to Claim 1, wherein the cooperating surface formations are arranged such that they can be disengaged by twisting the obturator through a small angle relative to the tube.
3. A medical tube assembly according to Claim 1 or 2, wherein the cooperating surface formations are provided by a resilient catch and a lip.
4. A medical tube assembly according to Claim 3, wherein said obturator has two resilient catches extending along opposite sides of the tube and engaging respective lips on the tube.
5. A medical tube assembly according to any one of the preceding claims, wherein said tube has a coupling at its machine end, and wherein the surface formation on the obturator is provided by at least one resilient catch that extends along the outside of the coupling and engages on a surface formation on the coupling.

6. A medical tube assembly according to any one of the preceding claims, wherein said obturator has a strap of rectangular section extending between its machine end and its patient end.
7. A medical tube assembly according to Claim 6, wherein the patient and machine ends of the obturator both have an air passage therethrough.
8. A medical tube assembly according to any one of the preceding claims, wherein said obturator is moulded from a plastics material.
9. A tracheostomy tube assembly comprising a tracheostomy tube and an obturator inserted within the tube, the obturator having a pointed patient end projecting from the patient end of the tube to aid insertion of the assembly, wherein the obturator and tube are provided at their machine ends with cooperating surface formations arranged, when engaged, to prevent rearward displacement of the obturator relative to the tube, and wherein said tube and obturator together provide an air passage extending along the assembly to enable the patient to breath while the assembly is being inserted.
10. A tracheostomy tube assembly substantially as hereinbefore described with reference to the accompanying drawings.
11. Any novel feature or combination of features as hereinbefore described.



Application No: GB 9716063.4  
Claims searched: 1-10

Examiner: Simon M. Fortt  
Date of search: 28 October 1997

**Patents Act 1977**  
**Search Report under Section 17**

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (RGEX, RGBB)

Int Cl (Ed.6): A61M 16/00, 16/04, 25/00.

Other:

**Documents considered to be relevant:**

Category	Identity of document and relevant passage	Relevant to claims
X	GB 2 161 709 A (WALLACE) p 2, ll 4-11 and ll 22-25; p 3 ll 27-33; figs. 1 and 3.	1, 3-5
X	EP 0 231 634 A2 (SHERWOOD MEDICAL CO.) col 2, l 48 - col 3, line 1; figs. 1 and 2.	1-5
A	WO 95/20419 A1 (MALLINCKRODT MEDICAL INC) whole document.	
X, Y	WO 95/16485 A1 (MALLINCKRODT MEDICAL INC.) p 12, ll 14-17; p 13, ll 3-7.	X:7-10 Y: 7
X, Y	US 5 222 487 (SMITHS INDUSTRIES MEDICAL SYSTEMS) col 6, ll 3-55; figs. 7-10.	X: 1-6 and 8-11 Y: 7
X	US 5 067 496 (SHILEY INC.) col 4, lines 54-64; fig. 4.	1, 3-5

X Document indicating lack of novelty or inventive step  
Y Document indicating lack of inventive step if combined  
with one or more other documents of same category.  
& Member of the same patent family

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the filing date of this invention.  
E Patent document published on or after, but with priority date earlier  
than, the filing date of this application.